

Exhibit 5



CARDINAL HEALTH INC



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DEA OVERVIEW AND DIVERSION DETECTION AND PREVENTION

CARDINAL DEA TRAINING



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DRUG ENFORCEMENT ADMINISTRATION (DEA)



- **DEVELOPMENTS IN REGULATORY CONTROLS**
 - **CHEMICALS**
 - **CONTROLLED SUBSTANCES**
 - **SUSPICIOUS ORDER MONITORING**
- **OPERATIONS**
- **MANAGEMENT/STRUCTURE**
- **RELATIONSHIP WITH REGISTRANTS**

DIVERSION CONCERNS



■ EXTENT OF PROBLEM

■ PHARMACEUTICAL DRUGS

- HYDROCODONE
- OXYCONTIN
- DILAUDID
- METHADONE
- ALPRAZOLAM
- DIAZEPAM
- PHENTERMINE

■ METHODS OF DIVERSION

- EMPLOYEE AND NON-EMPLOYEE THEFTS
- IN-TRANSIT LOSSES
- INDISCRIMATE PRESCRIBING
- FORGED PRESCRIPTONS
- DOCTOR SHOPPING
- PAIN CLINICS
- FINANCIERS
- ORDERS AND DISTRIBUTION



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DIVERSION CONCERNS - DC



- UNSECURED DRUGS IN THE RECEIVING/DISTRIBUTION AREAS
- POOR INVENTORY CONTROLS FOR DRUGS AWAITING DESTRUCTION
- ACCESS TO COMPUTER PROGRAMS TO CHANGE "ON HAND" BALANCES
- USE OF TRASH CANS/RECEPTACLES FOR DIVERSION
- INADEQUATE USE OF CAMERAS
- LACK OF ACCESS CONTROLS
- PERSONAL BELONGINGS



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RESPONSIBILITY



- **RECOGNITION AND PREVENTION**
 - **MANAGEMENT, SUPERVISORY AND STAFF RESPONSIBILITY**



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CONTROLLED SUBSTANCES ACT



- PASSED IN 1970, EFFECTIVE IN 1971
- ESTABLISHED THE CONCEPT OF A “CONTROLLED SUBSTANCE” WHICH INCLUDED BOTH OPIOIDS AND PSYCHOTROPIC SUBSTANCES
- PLACED WITHIN THE DEPARTMENT OF JUSTICE
- ESTABLISHED A “CLOSED SYSTEM”
- ONLY LEGALLY REGISTERED PERSONS MAY POSSESS CONTROLLED SUBSTANCES
- RECORDS MUST BE MAINTAINED WHEN CONTROLLED SUBSTANCES ARE TRANSFERRED FROM ONE REGISTRANT TO ANOTHER



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CONTROLLED SUBSTANCES ACT- continued



- DRUG SCHEDULES
- ORDER FORMS
- REGISTRATION
- PRESCRIPTIONS
- SECURITY
- IMPORT
- QUOTAS
- EXPORT
- RECORDS / REPORTS



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SCHEDULES



CONTROLLED SUBSTANCES



- **CONTROLLED SUBSTANCE**
 - **A DRUG OR OTHER SUBSTANCE, OR IMMEDIATE PRECURSOR, INCLUDED IN SCHEDULE I, II, III, IV OR V**
 - **OPIOIDS**
 - **SEDATIVES**
 - **STIMULANTS**
 - **DEPRESSANTS**
 - **HALLUCINOGENICS**
 - **ANABOLIC STERIODS**

CONTROLLED SUBSTANCES



- **SCHEDULE I**
 - NO LEGITIMATE MEDICAL USE – MARIJUANA, HEROIN, LSD
- **SCHEDULE II**
 - MORPHINE, OXYCODONE, AMPHETAMINES, METHYLPHENIDATE, SECOBARBITAL
- **SCHEDULE III**
 - HYDROCODONE AND CODEINE COMBINATION
- **SCHEDULE IV**
 - DIAZEPAM, LORAZEPAM
- **SCHEDULE V**
 - COUGH PREPARATIONS WITH CODEINE



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CONTROLLED SUBSTANCES SCHEDULING, DESCHEDULING, RESCHEDULING



■ FEDERAL

- FDA
- DEA

■ STATE

- AUTOMATIC
- ADMINISTRATIVE
- LEGISLATIVE

REGISTRATION



REGISTRATIONS



| | | |
|---|--|---|
| MANUFACTURING (SCHEDULE I - V) | DISTRIBUTION (SCHEDULE I - V) | DISPENSING / INSTRUCTION (SCHEDULE II - V) |
| CHEMICAL ANALYSIS (SCHEDULE I - V) | RESEARCH (SCHEDULE I - V) | IMPORT (SCHEDULE I - V) |
| EXPORT (SCHEDULE I - V) | NTP SCHEDULE II - V) | |

REGISTRATIONS



- SIGNATURE
 - INDIVIDUAL
 - PARTNERSHIP
 - CORPORATION
- POWER OF ATTORNEY
 - SUBMISSION
- COINCIDENT ACTIVITIES



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DISTRIBUTION CENTER RECORDS AND REPORTS



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GENERAL REQUIREMENTS



- **CONTROLLED SUBSTANCE RECORDS MUST BE AVAILABLE FOR INSPECTION**
 - **MAY REQUEST CENTRAL RECORDKEEPING FOR SOME RECORDS**
- **RECORDS MUST BE MAINTAINED FOR TWO YEARS**
- **SCHEDULE II RECORDS MUST BE MAINTAINED SEPARATE FROM OTHER RECORDS**
- **SCHEDULE III, IV AND V RECORDS MAY BE COMMINGLED WITH OTHER RECORDS IF THEY ARE “READILY RETRIEVABLE”**

CONTROLLED SUBSTANCES REQUIREMENTS



- **SCHEDULE II**

- **DEA FORM 222**

- **ELECTRONIC ORDERING**

- **RECEIVING AND DISTRIBUTION RECORD**

- **SUPPLIER/CUSTOMER NAME, ADDRESS AND DEA
REGISTRATION NUMBER, ACTUAL DATE OF
RECEIPT/DISTRIBUTION, DRUG NAME, STRENGTH,
DOSAGE FORM, QUANTITY AND NUMBER OF
COMMERCIAL CONTAINERS**

- **SCHEDULE III, IV AND V**

- **RECEIVING AND DISTRIBUTION RECORD**

CONTROLLED SUBSTANCES REQUIREMENTS - REPORTS



- **DEA 106**
 - **THEFT AND SIGNIFICANT LOSSES**
 - **ALL THEFTS MUST BE REPORTED WITHIN ONE BUSINESS DAY, IN WRITING, TO BE FOLLOWED BY A DEA 106**
 - **ONLY SIGNIFICANT LOSSES ARE TO BE REPORTED ON A DEA 106.**
 - **IN TRANSIT LOSSES TO BE REPORTED BY THE SUPPLIER**
- **DEA 41**
 - **DISPOSAL**
- **ARCOS**
 - **ERROR LISTINGS**



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CONTROLLED SUBSTANCES REPORTS



■ SUSPICIOUS ORDER MONITORING (SOM)

- EXCESSIVE QUANTITIES
- UNUSUAL FREQUENCY
- UNUSUAL SIZE
- ORDERS DEVIATING SUBSTANTIALLY FROM A
NORMAL PATTERN

■ REPORTING

■ SHIP – DON'T SHIP

CARDINAL'S SOM PROGRAM



- NEW CUSTOMER QUESTIONNAIRE TO BE COMPLETED BY THE PHARMACIST BUSINESS CONSULTANT AND REVIEWED AT CORPORATE BY THE DIVERSION CONTROL GROUP
 - ACCOUNT APPROVED AND OPENED
 - ACCOUNT NOT APPROVED PENDING ADDITIONAL INVESTIGATION
 - ACCOUNT DENIED



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CARDINAL'S SOM PROGRAM



- **COMPUTER ANALYSIS OF ORDERS**
 - **GROUPS DRUGS ACCORDING TO GENERIC INGREDIENT**
 - **COMPARES PURCHASES FOR LIKE ACCOUNTS**
 - i.e., HOSPITALS, GOVERNMENT RETAIL PHARMACY
 - **COMPARES PURCHASES FOR SIMILAR SIZE ACCOUNTS**
 - i.e., SMALL, MEDIUM AND LARGE ACCOUNTS, BASED UPON RX DOLLAR VOLUME
 - **COMPARES PURCHASES BASED UPON INDIVIDUAL DEA REGISTRATION NUMBER**
 - NOT BY ACCOUNT NUMBERS
 - **ORDERS FOR THREE TIMES THE AVERAGE ARE HELD/PENDED**
 - **ORDERS ARE ANALYZED IN REAL TIME**



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CARDINAL'S SOM PROGRAM



- PENDING ORDERS ARE REVIEWED BY THE DIVERSION CONTROL GROUP
 - INVESTIGATION FROM A REMOTE LOCATION (i.e., HEADQUARTERS)
 - ON SITE INVESTIGATION
 - COORDINATE WITH THE LOCAL DC
- CLEARED ORDERS ARE RELEASED
- IF NOT CLEARED, THE ORDER IS DEEMED SUSPICIOUS AND REPORTED TO THE DEA
- ONLY THE DIVERSION CONTROL GROUP CAN ADJUST THRESHOLDS FOR INDIVIDUAL ACCOUNTS



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INVENTORY AND INVENTORY ADJUSTMENTS



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CONTROLLED SUBSTANCES INVENTORY



■ INVENTORY

- **MUST BE TAKEN ONCE EVERY TWO YEARS**
- **SCHEDULE II MUST BE SEPARATE FROM SCHEDULE III, IV AND V**
- **ALL CONTROLLED SUBSTANCES INCLUDING**
 - **OUTDATES**
 - **HELD FOR DISPOSAL**
 - **DAMAGED**
- **MUST BE TAKEN AS OF THE OPEN OR CLOSE OF BUSINESS**
- **MUST BE AN EXACT COUNT**

TREND ANALYSIS



- **NEED FOR DOCUMENTATION, REVIEW AND APPROVAL PRIOR TO AN INVENTORY ADJUSTMENT**
 - **CONDUCT A REVIEW / INVESTIGATION**
 - **RECORDS MUST DOCUMENT**
 - **THE INVESTIGATION CONDUCTED / DEA-TYPE ACCOUNTABILITY**
 - **THE IDENTITY AND QUANTITY OF THE DRUGS**
 - **ENSURE THAT THE NUMBER OF EMPLOYEES IS LIMITED, AND A REPORT IS COMPLETED PRIOR TO THE ADJUSTMENT**
 - **THEFTS AND SIGNIFICANT LOSSES REQUIRE A REPORT TO THE DEA UPON DISCOVERY, WITHIN ONE BUSINESS DAY**



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SECURITY



CONTROLLED SUBSTANCES SECURITY



- **SCHEDULE II**
 - **VAULT**
 - **SAFE**
 - **LIMITED AND CONTROLLED ACCESS**
 - **DESIGNATED EMPLOYEE**
- **SCHEDULE III, IV AND V**
 - **CAGE**
 - **LIMITED AND CONTROLLED ACCESS**
 - **DESIGNATED EMPLOYEE**
- **CAMERAS**
- **ALARMS**
- **SHIPPING CONTAINERS**

QUESTIONABLE PRESCRIBING



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CONTROLLED SUBSTANCES QUESTIONABLE PRESCRIBING



- **ACUTE AND EPISODIC PAIN**
 - **PRESCRIBING SEVERAL DIFFERENT KINDS OF SHORT-ACTING OPIOIDS AT THE SAME TIME**
 - **PRESCRIPTIONS THAT GREATLY EXCEED THE MAXIMUM DAILY DOSAGE OF ACETAMINOPHEN (50MG/KG)**
 - **LONG-TERM PRESCRIBING OF OPIOIDS FOR A SHORT-TERM PROBLEM WITHOUT A DIAGNOSIS OF CHRONIC PAIN**
- **CHRONIC PAIN**
 - **ROUTINE PRESCRIBING AND DISPENSING OF DRUGS NOT RECOMMENDED FOR CHRONIC PAIN**
 - **HIGH VOLUME PRACTICE**
 - **POOR NOTES**
 - **FAILURE TO DOCUMENT AN APPROPRIATE REASON FOR PRESCRIBING OPIOIDS**



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CONTROLLED SUBSTANCES QUESTIONABLE PRESCRIBING



■ CHRONIC PAIN (CONTINUED)

- FAILURE TO ABIDE BY FEDERAL AND STATE CONTROLLED SUBSTANCE LAWS AND REGULATIONS**
- PRESCRIBING MANY TYPES OF DRUGS WITH ABUSE POTENTIAL FOR ONE PATIENT**
- PRESCRIBING OR DISPENSING TO SUSPICIOUS INDIVIDUALS**
- PRESCRIBING CONTROLLED SUBSTANCES TO SELF OR FAMILY MEMBERS**

PHARMACY DISPENSING



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CONTROLLED SUBSTANCES PHARMACY DISPENSING



■ PHARMACIST RESPONSIBILITY

- **LEGAL RESPONSIBILITY – STATE AND FEDERAL REQUIREMENTS FOR DISPENSING CS**
- **PERSONAL RESPONSIBILITY – PROTECT YOUR PRACTICE FROM BECOMING AN EASY TARGET FOR DRUG DIVERSION**
- **CONSTANT VIGILANCE AGAINST FORGED AND ALTERED PRESCRIPTIONS**

■ FRAUDULENT PRESCRIPTIONS

- **ALTERATION OF PRESCRIPTIONS**
- **FORGED PRESCRIPTIONS**
- **NON-MEDICAL**

CONTROLLED SUBSTANCES PHARMACY DISPENSING



- **POSSIBLE INDICATION OF NON-MEDICAL PRESCRIBING**
 - PRESCRIBER WRITES SIGNIFICANTLY MORE PRESCRIPTIONS (OR IN LARGER QUANTITIES) COMPARED TO OTHER PRACTITIONERS IN THE AREA
 - THE PATIENT APPEARS TO BE RETURNING TOO FREQUENTLY
 - THE PRESCRIBER WRITES PRESCRIPTIONS FOR ANTAGONISTIC DRUGS, SUCH AS DEPRESSANTS AND STIMULANTS, AT THE SAME TIME
 - PATIENT APPEARS PRESENTING PRESCRIPTIONS WRITTEN IN THE NAMES OF OTHER PEOPLE
 - A NUMBER OF PEOPLE APPEAR SIMULTANEOUSLY, OR OVER A SHORT TIME, ALL BEARING SIMILAR PRESCRIPTIONS FROM THE SAME PHYSICIAN
 - NUMEROUS "STRANGERS," PEOPLE WHO ARE NOT REGULAR PATRONS OR RESIDENTS OF THE COMMUNITY, SUDDENLY SHOW UP WITH PRESCRIPTIONS FROM THE SAME PHYSICIAN

CONTROLLED SUBSTANCES PHARMACY DISPENSING



- **CHARACTERISTICS OF FORGED PRESCRIPTIONS**
 - **PRESCRIPTION LOOKS TOO GOOD – TOO LEGIBLE**
 - **QUANTITIES, DIRECTIONS OR DOSES DIFFER FROM USUAL MEDICAL USAGE**
 - **PRESCRIPTION DOES NOT COMPLY WITH THE ACCEPTABLE STANDARD ABBREVIATIONS**
 - **PRESCRIPTIONS APPEARS TO BE PHOTOCOPIED**
 - **DIRECTIONS WRITTEN IN FULL WITH NO ABBREVIATIONS**

CONTROLLED SUBSTANCES PHARMACY DISPENSING



■ PREVENTION TECHNIQUES

- **KNOW THE PRESCRIBER AND SIGNATURE**
- **KNOW THE PRESCRIBER'S DEA REGISTRATION NUMBER**
- **KNOW THE PATIENT**
- **CHECK THE DATE ON THE PRESCRIPTION ORDER. HAS IT BEEN PRESENTED IN A REASONABLE LENGTH OF TIME**
- **DRUGS PRESCRIBED**
- **DISCUSS TREATMENT WITH PHYSICIAN**
- **DRUG TESTING**
- **PATIENT AND PHYSICIAN CONTRACTS**
- **PHYSICIAN AND PHARMACY CONTRACTS**

DC PREVENTION TECHNIQUES



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CONTROLLED SUBSTANCES DC PREVENTION TECHNIQUES



- **PREVENTION TECHNIQUES**
 - **KNOW THE PHARMACY**
 - **LOCATION**
 - **PHYSICIANS AND CLINICS IN AREA**
 - **TYPES**
 - **TYPES OF CUSTOMERS**
 - **LOITERING**
 - **ORDERING PATTERN**
 - **TYPES OF DRUGS**
 - **MONITOR ORDERS**
 - **FREQUENCY**
 - **SIZE**
 - **CHECK THE DATE ON THE ORDER. HAS IT BEEN A REASONABLE LENGTH OF TIME**

Q&A

